Application No. 10/693,166 Amdt Dated August 27, 2008 Reply Office action of October 18, 2007

REMARKS

In light of allowance of claims to the same crystal form in pending case Application No. 10/746,697, the Applicants are cancelling all claims to the crystalline form and only maintaining claim 99 to a formulation. Claims 103 to 107 have been added. These amendments were necessary because claim 99 depended on claims that have now been canceled. The new claims incorporate the features of the canceled claims.

A terminal disclaimer over this case is being filed in the Application No. 10/746,697. A courtesy copy is attached.

Accordingly, it is believed that claims 99, and 103 to 107 are now in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 10-0600.

Respectfully submitted,

Date: August 27, 2008

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PTO/SB/25 (09-06) Approved for use through 03/31/2007. OMB 0651-0031
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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

Docket Number (Optional) 01662/611056

In re Application of: FRENKEL et al.

Application No.: 10/746,697

Filed: December 24, 2003

For: Crystalline Form of Nateglinide

The owner*, Teva Pharmaceutical Industries, Ltd., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number 10/693,166 filed on October 23, 2003, defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that: any such patent: granted on the pending reference application:

expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. 🗆 The undersigned is an attorney or agent of record. Reg. No.

STATEMENT UNDER 37 CFR 3.73(b)

We hereby declare that Teva Pharmaceutical Industries Ltd. is the assignee of the entire right, title, and interest in the patent application identified above by virtue of the assignment from the inventor(s) of said patent application executed on March 15, 2004, March 15, 2004, and March 15, 2004. The assignments were recorded in the United States Patent and Trademark Office at Reel 015789, Frame 0357.

Signature Alon Shainberg

Typed or printed name

Assistant, General Patent Counsel

Yehudza Livneh, Ph.D.

Typed or printed name General Patent Counsel

Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assigner (owner).

Form PTO/SB/96 may be used for making this certification. See MPEP '324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 tand by the USF 10 to process) an application. Conjudentiality is governoo by 35 U.S.C. 122 and 37 CTR 1.11 and 1.14. Inits consection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOTE SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. PTO/SB/25 (09-04)